GABA Therapeutics, Inc. – February 2025

Next-Generation Anxiety Treatment

gaba THERAPEUTICS

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The forward-looking statements and projections contained in this presentation are expressly qualified by this cautionary statement. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, after the date on which the statements are made or to reflect the occurrence of unanticipated events. Readers are cautioned not to place undue reliance on forward-looking statements or projections. Prospective investors should not construe the contents of this presentation as legal, tax, investment or other advice. All prospective investors should make their own inquiries and consult their own advisors as to legal, tax, investment, and related matters concerning an investment in the securities of the Company

Investment Highlights

- GRX-917 is a deuterated analog of an anxiety drug shown to be safe and effective
- GRX-917 is a potentially superior treatment for anxiety:
  - Rapid onset and potential gold-standard efficacy
  - Without sedation, ataxia, cognitive impairment
  - No addiction liability
- Phase 2/3 ready – approval for GAD projected by 2028
- Additional indications include depression, epilepsy, pain and obesity
- U.S. patent exclusivity through at least 2042

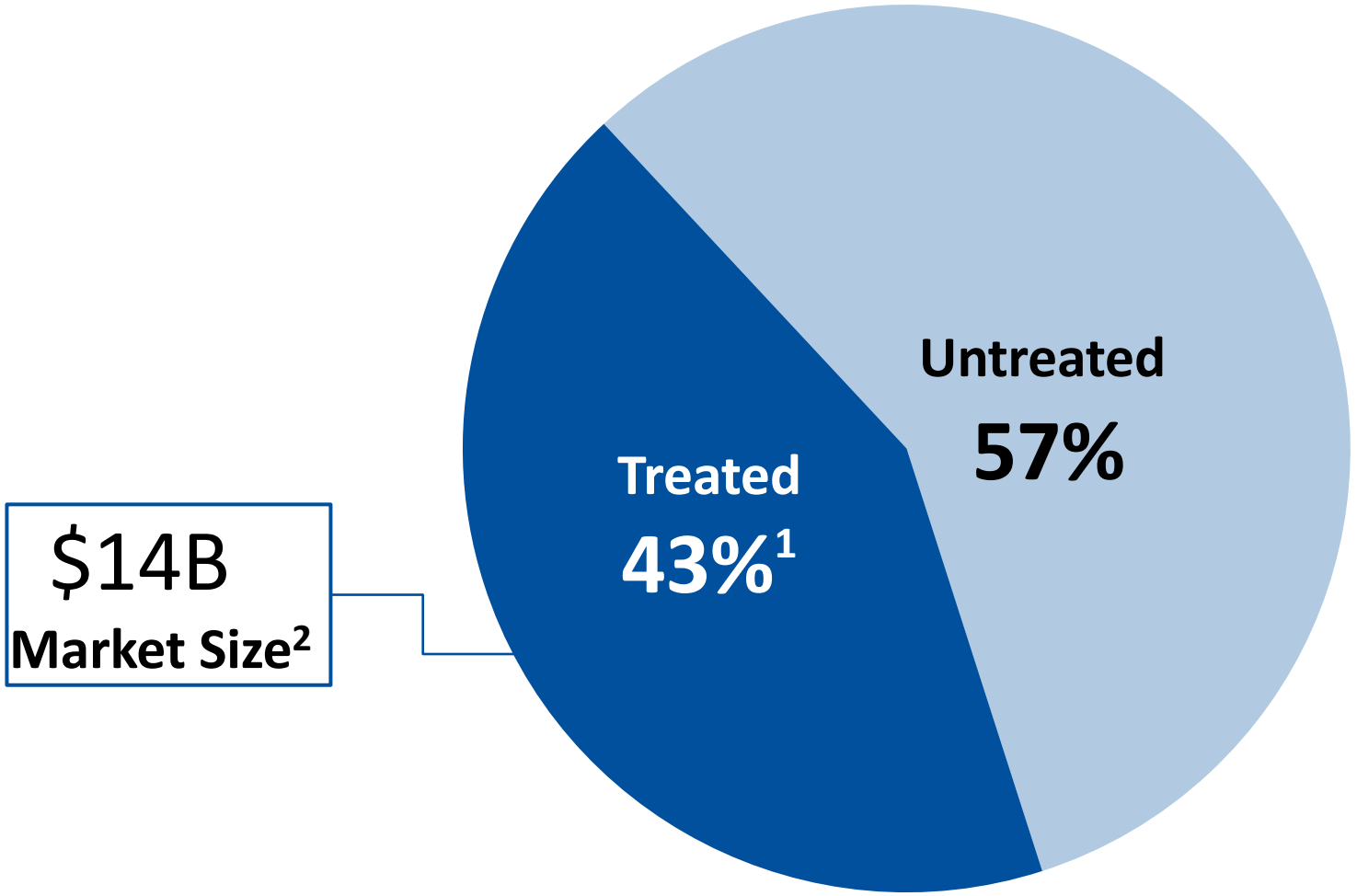
✓	Target Engagement
✓	Pharmacokinetics (PK)
✓	Safety
✓	Efficacy
✓	Commercial Differentiation

GRX-917: Pipeline-in-a-Drug

Ready to start clinical trials in multiple indications

[1]Supported by MOA and preclinical data

Most GAD Patients Don’t Receive Treatment



[1]Anxiety and Depression Association of America (2024)
[2]Global Anxiety Market: IMS, per Foster Rosenblatt Market Research

GRX-917 vs. Current Available Treatments

Key Attributes	GRX-917	SSRIs/SNRIs	Benzodiazepines
Rapid Onset	✓	4-8-week delay	✓
Efficacy	✓	Inferior	✓
Side Effects	✓	GI, sexual dysfunction, insomnia, weight gain	Sedation, ataxia, impaired cognition
Addiction Liability	✓	✓	X
Chronic Usage	✓	✓	X

GRX-917 Is Deuterated Etifoxine

Stresam®
Etifoxine

TID

- A safe, fast and effective anxiety medication
- Approved in France (1979)
- Substantial patient exposures[1]
- 100+ published studies

Improved PK via deuteration

GRX-917
Deuterated etifoxine

QD

- Identical MOA
- Comparable safety & efficacy
- Potentially improved compliance
- New chemical entity

[1]Based on management's extrapolation of 2000 - 2012 scripts in France (Source: IQVIA)

Deuterium Switch Strategy Has a Strong Track Record of Success

Successful Outcomes from Deuterated Products

teva
Austedo (deutetrabenazine) 6 mg, 9 mg, and 12 mg tablets
~$1.6B[1]
2024 est.

Bristol Myers Squibb
SOTYKTU (deucravacitinib) 6 mg tablets
$240M[2]
2024 est.

VERTEX
alyftrek
(Vanzacaftor/Tezacaftor/Deutivacaftor)
FDA Approved
Dec 2024

teva
AUSPEX PHARMACEUTICALS
$3.2B
2015

Otsuka
AVANIR pharmaceuticals
$3.5B
2014

GSK
CoNCERT Pharmaceuticals Inc.
D-atazanavir
$1B+
2009

Deuteration can:

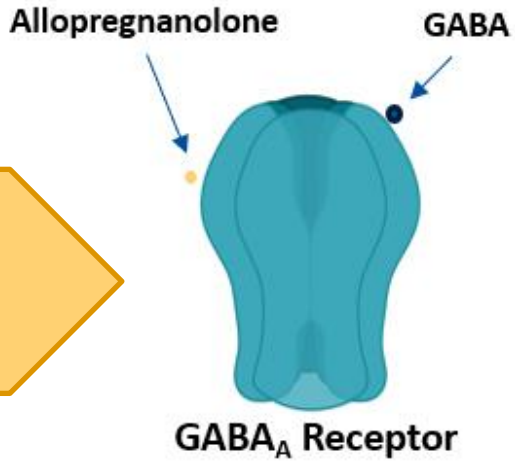
- ✓ Improve drugs
- ✓ Minimize risk in product development

[1]Per Teva FY 2024 Guidance
[2]Per broker consensus projections (Source: FactSet)

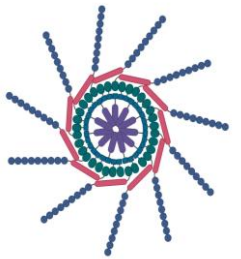
Novel Mechanism of Action

GRX-917/etifoxine increase neurosteroid synthesis[1]

Neurosteroids modulate receptors[2]
(anxiety, depression, epilepsy)



Neurosteroids inhibit NLRP3 inflammation[3]
(epilepsy, MS, pain, obesity)



[1]do Rego JL et al (2015) PLoS ONE 10(3): E0120473 ; internal data
[2]Lambert et al (2003) Prog Neurobiol 71(1); 67-80.
[3]Osmond et al (2023)

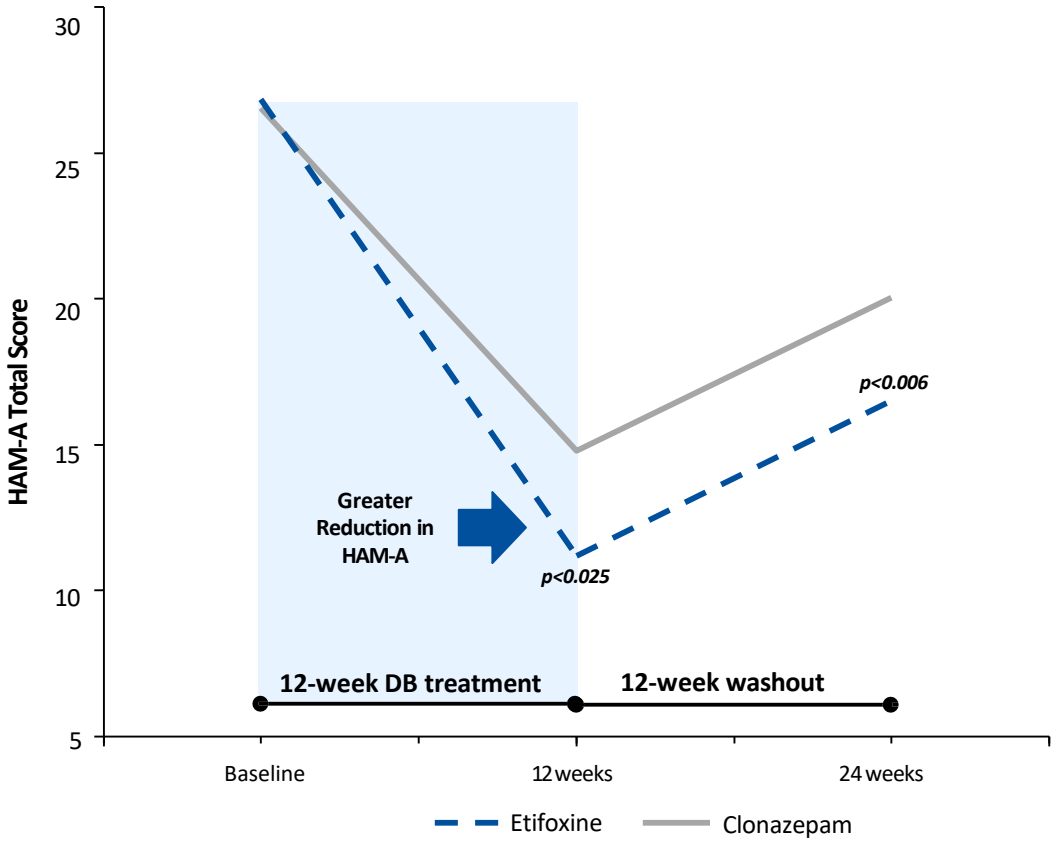
Etifoxine's Anxiolytic Efficacy is Well-Established

	Date	Clinical Study	Reference	N	Duration	Cohort	HAM-A	CGI scale	Result
1	1978	ETX vs Clobazam	S.132/GB	26	Not Available	Anxiety[1]	ETX = > Clobazam[2]		Marketing Authorization (France)
2	1978	ETX vs Clobazam	S.134/GB	20	Not Available	Anxiety[1]	ETX = > Clobazam[2]		Marketing Authorization (France)
3	1978	ETX vs Sulpiride vs Placebo	S.135/GB	23	Not Available	Anxiety[1]	ETX = > Sulpiride & Placebo[2]		Marketing Authorization (France)
4	1978	ETX vs Clobazam	S.137/GB	69	Not Available	Anxiety[1]	ETX = > Clobazam[2]		Marketing Authorization (France)
5	1978	ETX vs Placebo	S.139/GB	24	Not Available	Anxiety[1]	ETX = > Placebo[2]		Marketing Authorization (France)
6	1998	Etifoxine vs Buspirone	STRETI S.226/GB	170	31 days	ADWA	ETX > Buspirone	ETX > Buspirone	Superior efficacy to Buspirone
7	2006	Etifoxine vs Lorazepam (Ativan®)	ETILOR S.392/EN	191	28 days	ADWA	ETX = LZP (Ativan®)	ETX > LZP (Ativan®)	Comparable onset and efficacy to Lorazepam
8	2010	Etifoxine vs Phenazepam	Aleksandrovsky[3]	90	6 weeks	Adaption Disorder	ETX > Phenazepam	ETX > Phenazepam	Superior efficacy to Phenazepam
9	2015	Etifoxine vs Alprazolam (Xanax®)	ETIZAL S.650/EN	202	28 days	ADWA	ETX = ALP (Xanax®)	-	Comparable onset and efficacy to Alprazolam
10	2020	Etifoxine vs Clonazepam (Klonopin®)	Vicente[4]	179	24 weeks	GAD, PD, Phobias[5]	ETX = Clonazepam (Klonopin®)	ETX = Clonazepam (Klonopin®)	Superior efficacy to Clonazepam
11	2020	Etifoxine vs Lorazepam & Placebo	AMETIS ETI178	623	4 weeks	ADWA	Total HAM-A score reduction similar between ETX, lorazepam, placebo. EMA conclusion: "The decrease in HAM-A score in the etifoxine group was marked and clinically significant (52.6% reduction)."		
12	2022	EMA CHMP Etifoxine Assessment Report	EMA/CHMP 148255/2022	N/A	N/A	All available ETX data	"… the Committee considers that the benefit-risk balance of etifoxine remains favourable…" ETX was re-authorized for anxiety in France in Jan 2022 (29-1 vote).		

1. Various types of anxiety associated with psychological and somatic disturbances in diverse patient populations
2. "Results generally showed that etifoxine has similar or superior efficacy to active comparators or placebo for treating anxiety" per EMA/148255/2022 CHMP ETX Assessment

3. Aleksandrovsky et al., "Russian Psychiatric Journal"; Therapy of the mentally ill; No. 1; 2010; 74-78 Vicente et al.,
4. Psychopharmacology 237, 3357–3367 (2020)
5. Phobias categorized as agoraphobia, social phobia and specific phobias

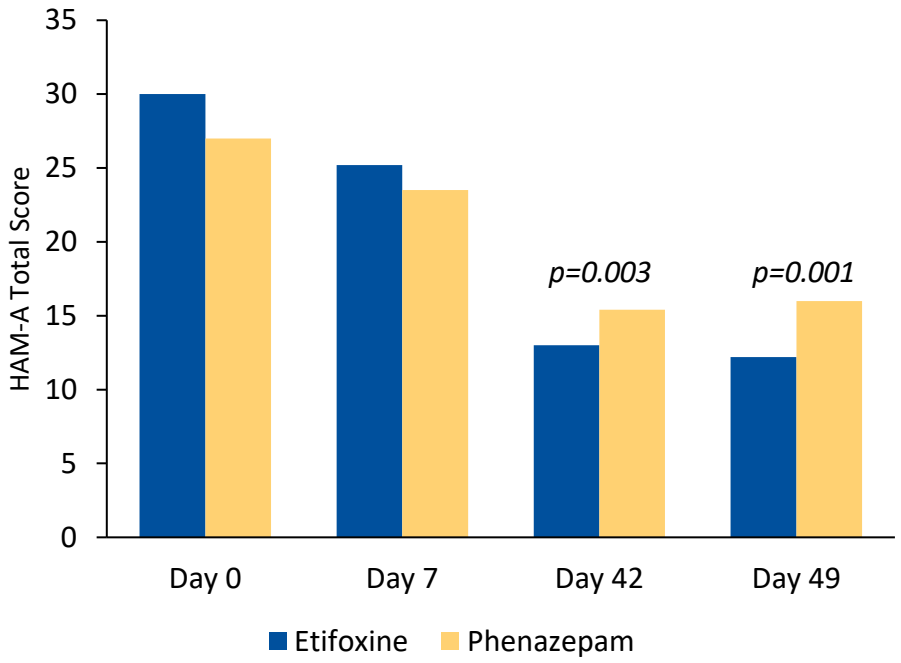
Etifoxine: Superior Efficacy vs. Clonazepam



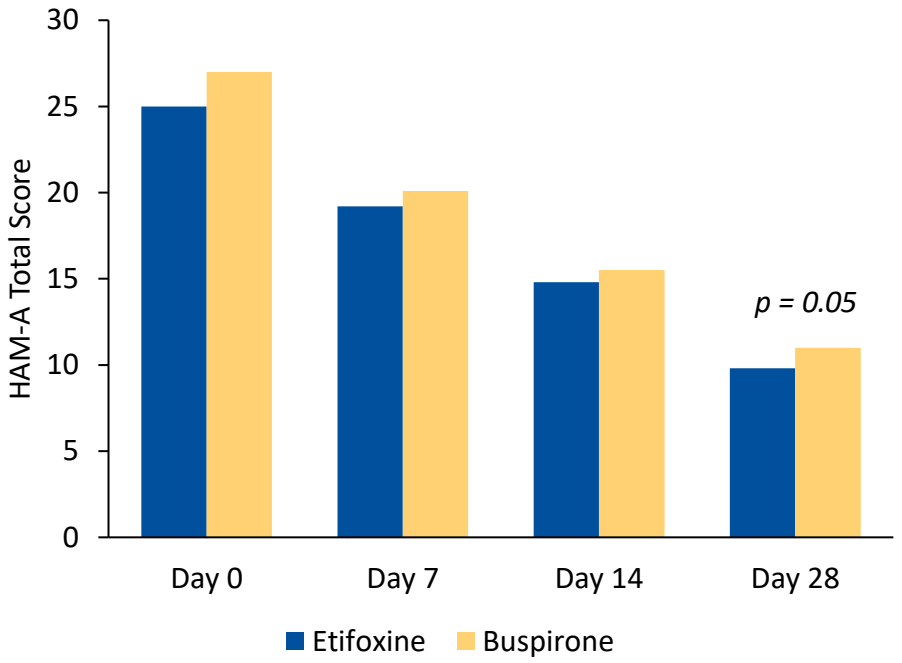
- Etifoxine demonstrated superior HAM-A reduction vs. clonazepam after 12-week treatment ($p<0.025$)
- Superior efficacy maintained following 12-week washout ($p<0.006$)

- Vicente et al. (2020) Psychopharmacology
- Double-blind, parallel, randomized, active controlled study; multiple anxiety disorders including GAD; N=179
- Etifoxine 50 mg TID v clonazepam 1 mg QD; 12-week treatment; 12-week washout

Etifoxine: Superior Efficacy vs. Phenazepam and Buspirone

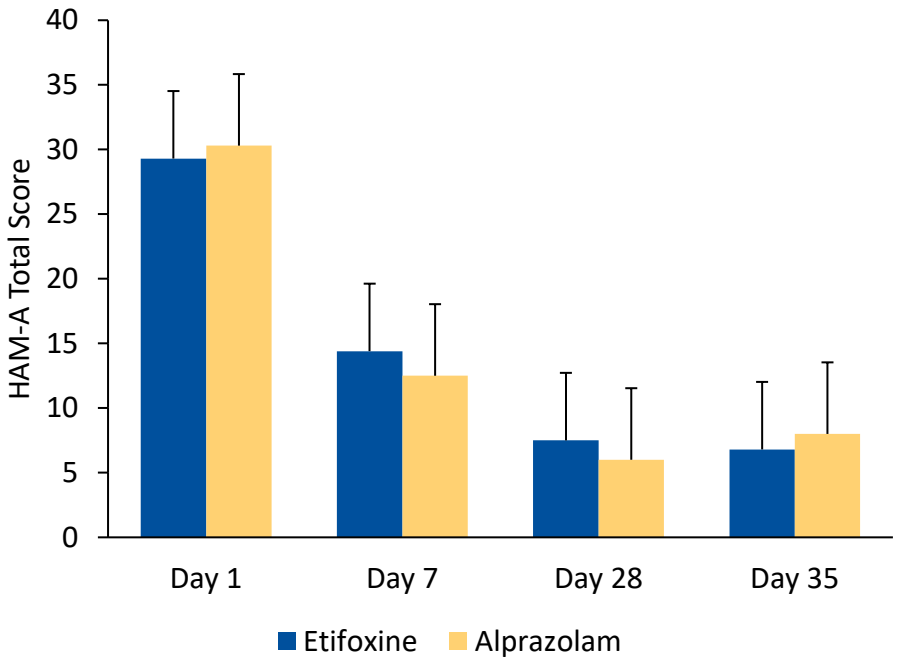


- Aleksandrovsky et al. (2010) Rus Psych J (1); 74-78.
- Randomized, parallel, open label, active controlled study; N=90;
- Adjustment Disorders
- Etifoxine (50 mg +100 mg) v phenazepam (0.5 mg BID); 6-week treatment

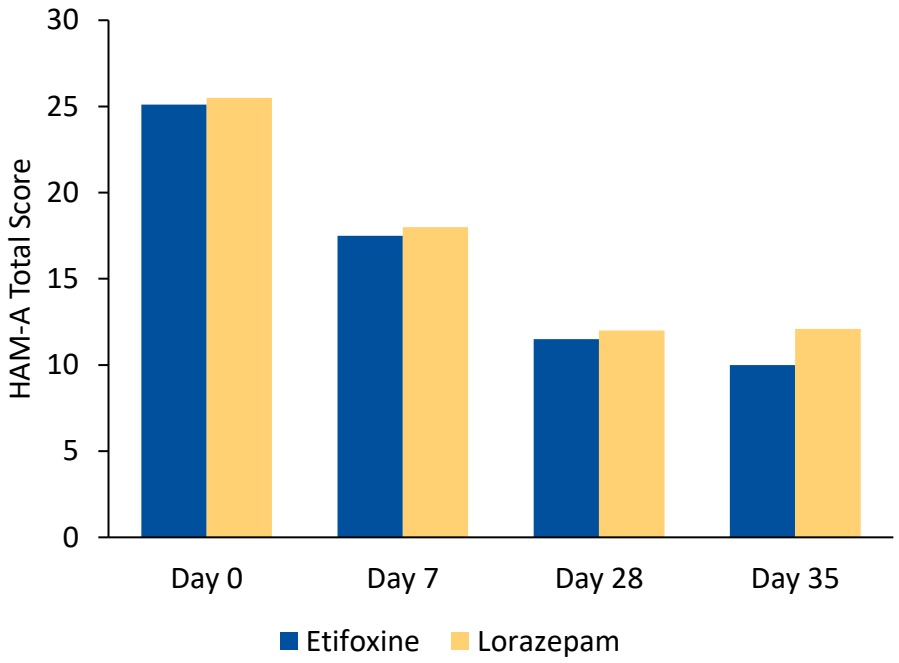


- Servant et al. (1998) Encephale 24(6):569-74.
- Double-blind, parallel, randomized, active controlled; N=170;
- Adjustment Disorder with Anxiety (ADWA)
- Etifoxine (150-200 mg/day) v buspirone (15-20 mg/day); 4-week treatment

Etifoxine: Comparable Efficacy to Leading Benzodiazepines



- Stein et al. (2015); N=202; ADWA
- Double-blind, randomized, parallel, active controlled 4-week treatment
- Etifoxine (150 mg/day) v. alprazolam (1.5 mg/day)



- Nguyen et al. (2006); N=191; ADWA
- Double-blind, randomized; parallel, active controlled 4-week treatment
- Etifoxine (50 mg TID) v lorazepam (2 mg/day)

Etifoxine's Safety Profile is Well-Established

Adverse Event	Comment	Source
Non-Addictive	"No cases of abuse, misuse or pharmacodependence."	Cottin et al[1] (based on +15M Rx)
No Sedation	No effects on vigilance or psychomotor performance	Micallef et al[2]
No Impaired Cognition	No effect on alertness or other cognitive parameters in elderly	Deplanque et al[3]
Serious Adverse Drug Reactions (ADRs)	Very rare ADRs not consistent with causation (1-2 per +15M Rx)	PV Analysis of Etifoxine Serious ADRs in EudraVigilance Database[4]

1. Cottin et al., Fundamental & Clinical Pharmacology 30 (2016) 147–152
2. Micallef et al., 2001 Blackwell Science Fundamental & Clinical Pharmacology 15 (2001) 209-216
3. Deplanque et al., European Neuropsychopharmacology (2018) 28, 925-932
4. Kinexum-Pharmacovigilance Analysis of Etifoxine 2023-03-13

Phase 1 Program: GRX-917 vs. Etifoxine

Safe, well-tolerated, with minimal adverse events

Nervous System Disorders	GRX-917 (n=75)	Placebo (n=25)
Dizziness	4%	4%
Headache	17%	12%
Paresthesia	1%	4%
Somnolence	0%	8%
Ataxia	0%	0%
Lethargy	3%	0%
Cognitive Deficit	0%	0%

GRX-917 demonstrated improved PK and once-daily dosing

	Etifoxine	GRX-917
Half-life	4 hours	>12 hours
Daily dose	200 mg	60 mg
Dosing regimen	TID	QD

Etifoxine Phase 1: (Study GRX-ETI-001) - A Two Stage, Double-Blind, Placebo-Controlled Single and Multiple Dose Study To Evaluate The Pharmacokinetics, Pharmacodynamics, and Safety of Oral Etifoxine in Normal Healthy Volunteers

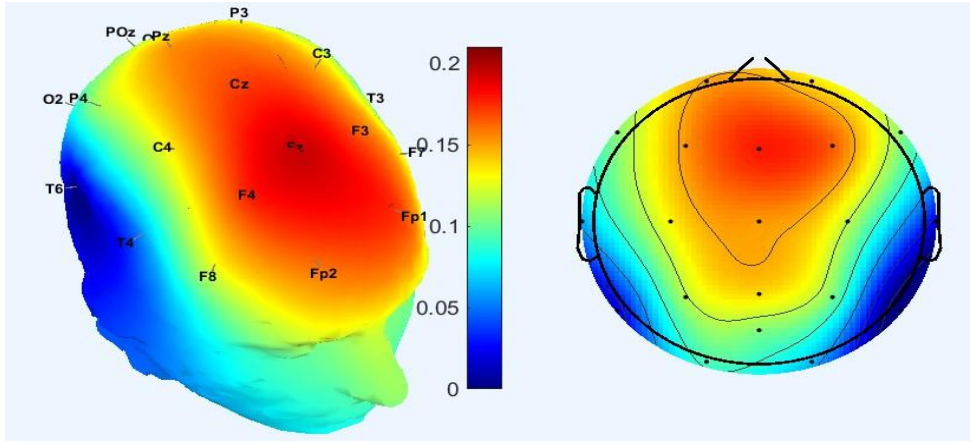
GRX-917 Phase 1: (Study GRX-917-01) - A Phase 1, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Single and Multiple Ascending Doses of GRX-917 in Healthy Adult Subjects

Phase 1: GRX-917 Activates an Established Anxiolytic Biomarker

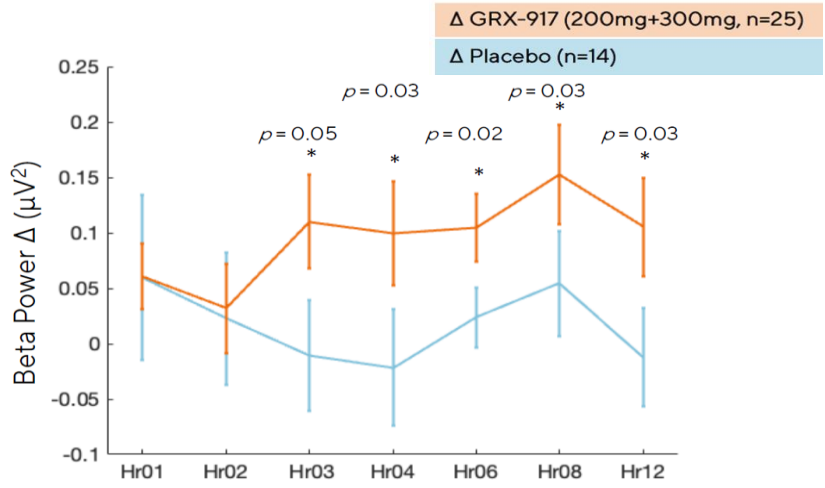
- GRX-917 increases qEEG Beta Power:
  - Exposure-dependent
  - Dose- and time-dependent
  - Rapid and sustained

- qEEG Beta Power increased signal suggests:
  - $GABA_A$ receptor target engagement
  - Anxiolytic efficacy

GRX-917 Exposure Response Heat Map (p<0.0001)



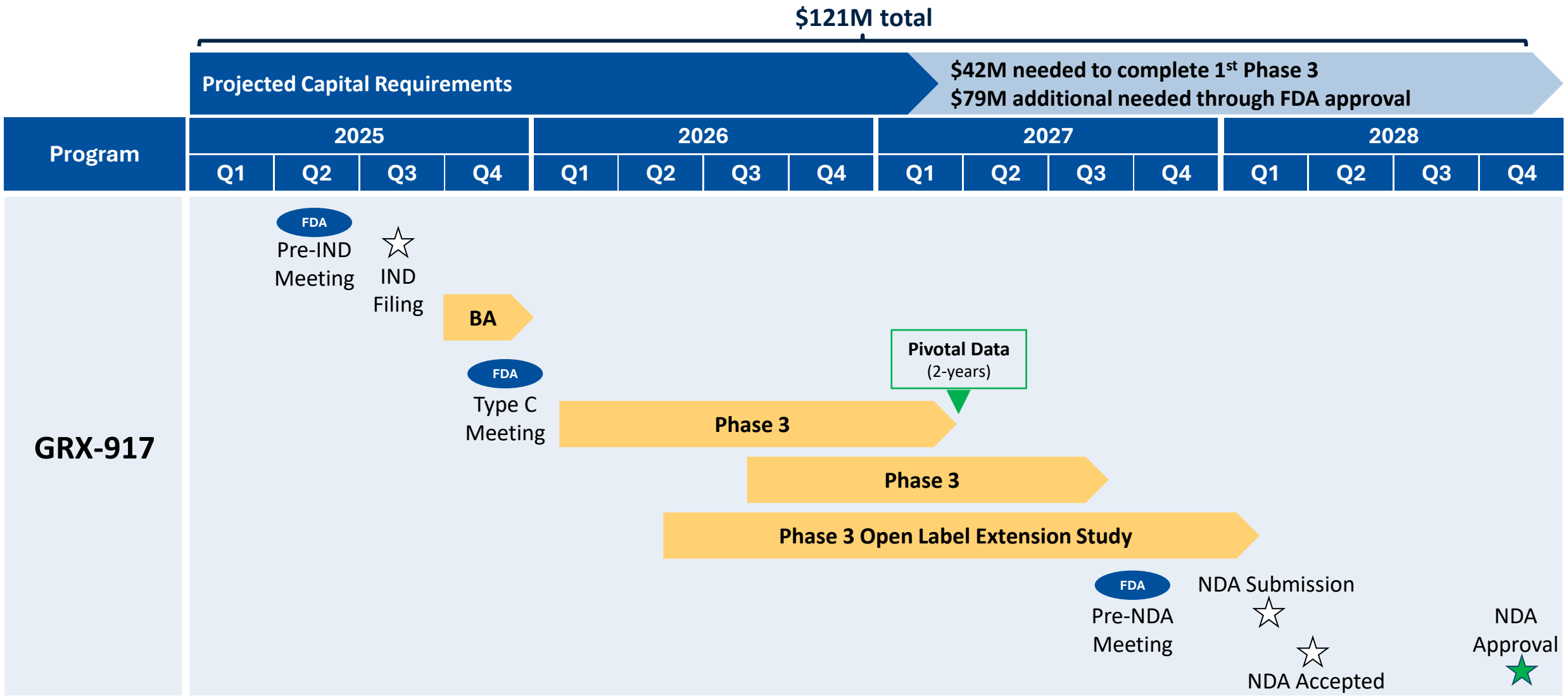
GRX-917 vs. Placebo (p<0.05)



GRX-917 Phase 1: (Study GRX-917-01) - A Phase 1, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Single and Multiple Ascending Doses of GRX-917 in Healthy Adult Subjects

GAD Clinical Program

NDA Projected by 2028



FDA FDA meeting ☆ FDA Milestone ★ NDA Approval

Capital Requirements and Use of Funds

$ in millions

Use of Funds	1st Phase 3 GAD (Q1, 2027)	Total to NDA (est. 2028)
IND Opening Studies	$4.5	$4.5
Clinical Trials	$19.0	$58.0
Tox & Research	$4.3	$10.6
CMC	$0.6	$18.2
Regulatory	$0.5	$2.5
G&A	$13.5	$27.7
Total	**$42.0**	**$121.0**

All costs supported by vendor quotes

Key Milestones

Accomplished to Date

Phase 1 Etifoxine (Non-deuterated Analog)

- Safety and tolerability
- qEEG biomarker demonstrating anxiolytic efficacy
- PK/dosing benchmarking for GRX-917

Phase 1 GRX-917

- Safety and tolerability
- qEEG biomarker demonstrating anxiolytic efficacy

GRX-917 Oral Formulation

- Phase 2/3 ready

2025

Q2 2025:

- Pre-IND meeting

Q3 2025:

- IND filing

Q4 2025:

- Start bioavailability study
- BA data readout

NIH Preclinical GRX-917 Data

- Pain
- Epilepsy

2026 - 2028

Q1 2026:

- Start 1st Phase 3 pivotal trial

Q3 2026:

- Start 2nd Phase 3 pivotal trial

Q1 2027:

- 1st Phase 3 data

Q3 2027:

- 2nd Phase 3 data

Q1 2028:

- NDA Submission

Intellectual Property Overview

- **Robust IP portfolio with composition patent protection through at least 2036**
- **Potential Hatch-Waxman extensions through 2042**

Composition of matter patent protection in US, Australia, Canada, Brazil, China, EU, UK, Israel, Japan, South Korea, Mexico, with patent pending in India.

Name / Description	Patent	Status	Expiry
Deuterated Analogs of Etifoxine and Methods of Administration Without Autoinduction of Metabolism	U.S. Application No. 18/493,488	Published	10/24/2043
Deuterated analogs of etifoxine, their derivatives and uses thereof	US Patent No. 11,672,805	Issued	3/18/2036
Deuterated analogs of etifoxine, their derivatives and uses thereof	U.S. Patent No. 10,080,755	Issued	3/18/2036
Deuterated analogs of etifoxine, their derivatives and uses thereof	U.S. Patent No. 10,736,901	Issued	3/18/2036
Enantiomerically pure S-etifoxine, pharmaceutical compositions thereof and methods of their use	U.S. Patent No. 8,110,569	Issued	10/1/2027

Key Executives

Decades of successful leadership, clinical development, and commercialization in pharma and biotech

Mario Saltarelli, M.D., Ph.D.
Chief Executive Officer,
Director

Pfizer
Abbott
Shire
Johns Hopkins School of Medicine

Richard Farrell
Chief Financial Officer,
Director, & Co-Founder

EY
Deloitte.

Kathryn King, Ph.D.
Chief Operating Officer

Abbott
abbvie
Takeda
APTINYX

David Putnam, Ph.D.
Chief Scientific Officer,
Co-Founder

Roche
ucb

Olivier Dasse, Ph.D.
Senior VP of Chemistry,
Co-Founder

ucb

Key Advisors

Decades of successful leadership in pharma development, psychiatry, and regulatory

Robert Berman, M.D.
Scientific Advisory Board Chairman
Co-Founder, Biohaven

biohaven pharmaceuticals

Bristol Myers Squibb

Pfizer

Yale SCHOOL OF MEDICINE

Maurizio Fava, M.D.
Clinical & Regulatory Advisor
Psychiatrist-in-Chief
Mass General/ Harvard Med

MASSACHUSETTS GENERAL HOSPITAL
PSYCHIATRY

Thomas Laughren, M.D.
Clinical & Regulatory Advisor
Former Director, Div. Psych Products, FDA/CDER

FDA

MASSACHUSETTS GENERAL HOSPITAL
PSYCHIATRY

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